REMARKS

Claim Amendments

The three independent claims, claims 1, 12, and 25, have been amended to add the limitation that the dressing is prepared by "allowing the reaction mixture to gel at 20-37 degrees Celsius." The added limitation is supported by the specification as explained below, and the added limitation is not disclosed in the Berggren reference cited in one of the Examiner's § 102 rejections and all three of the Examiner's § 103 rejections. In fact, Berggren "teaches away" from a reaction mixture that gels at 20-37 degrees Celsius. Thus, it is believed that the amendments overcome those four rejections.

In addition, the applicant respectfully argues that the Examiner's second § 102 rejection (anticipation by Smestad) is overcome by the limitation "bioresorbable" contained in independent claim 12.

It is therefore believed that pending claims 1-10, 12-14, 16-20, and 25-29 are in condition for allowance.

35 U.S.C. § 102(b) Rejection: Berggren et al.

Claims 12-13 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren"). Claim 12 has been amended to include an additional limitation to overcome this rejection. As amended, claim 12 now requires that the reaction mixture used to make the flowable dressing is allowed to gel at 20-37 degrees Celsius. This limitation is not disclosed in Berggren; furthermore, Berggren specifically states that the disclosed material cannot be a gel below 38 degrees Celsius. Thus, the Applicant's claimed invention is now substantially different than what is disclosed in Berggren.

The Examiner notes that Berggren, like the Applicant, discloses "a syringe comprising a flowable, moldable biocompatible gel prepared by a collagen derivative and a non-cytotoxic cross-linking agent." OA at 3. However, the Examiner also notes that the Berggren compositions are flowable and thus meet the limitation of the instant claims only "when the compositions are heated." OA at 2 (citing Berggren col. 5, lines 35-40). The Examiner further explains that the disclosed material is "less or non-flowable at or below body temperature and a flowable polymer at a physiologically compatible elevated temperature which ranges from 38°C to 75°C." OA at 2 (citing Berggren, col. 4 lines 65-67).

Berggren discloses a material that is heated in order to produce a flowable, injectable formulation (col. 4 line 43). Once injected into the biological pocket, the material cools to a more viscous consistency "with sufficient cohesiveness to be retainable in the biological pocket" (col. 4 lines 45-47). The cooled material in the tissue pockets must be "unlike gels or solutions or other fluids" when cooled to the temperature of the pocket, which Berggren implies is 37 degrees Celsius (col. 4 lines 47-48, 61-66).

Thus, the material disclosed in Berggren is heated to a "physiologically compatible elevated temperature" to allow it to be injected as a flowable fluid (col. 5 lines 35-39). The material is in the form of "a gel or a viscous fluid" only at a "physiologically compatible elevated temperature which allows insertion or injection into the periodontal pocket by means of a syringe" (col. 10 lines 11-14). Berggren teaches that a "physiologically compatible elevated temperature" is between 38 and 75 degrees Celsius, preferably 38 to 55 degrees Celsius (col. 4 lines 54-67). Berggren discloses several methods for heating the material to these required temperatures (col. 10 lines 17-54).

Although the material is flowable at these temperatures, Berggren teaches that the material must be "less to non-flowable (that is, the material sets up and will not easily flow out of the container) when the material is at the body temperature of the host animal" (col. 5 lines 63-66). This is necessary so that the "less to non-flowable mass will remain in the periodontal pocket when at the body temperature of the host animal" (col. 10 lines15-17). Berggren, then, teaches that the disclosed material cannot be a gel at a temperature below 38 degrees Celsius.

The Applicant's amendments limiting the temperature at which the reaction mixture is allowed to gel are a proper range limitation, because one skilled in the art would recognize from the original specification that the Applicant invented the process that includes the new limitations. See MPEP § 2163.05 (III).

Claim limitation ranges do not have to be described exactly in the specification; instead, the specification must simply show one skilled in the art that the applicant possessed an invention including the claim limitation ranges. See *Union Oil of California v. Atlantic Richfield*, 208 F.3d 989, 997 (Fed. Cir. 2000).

For example, in *In re Wertheim*, an inventor disclosed in the specification a concentration for a coffee extract of between 25 and 60 % solid matter, with specific examples containing 36% and 50 % solid matter. 541 F.2d 257, 262 (C.C.P.A. 1976). The court held that claim range limitations are proper if one skilled in the art would recognize from the disclosure that the invented process included those limitations. *Id.*

Thus a claim range of "at least 35% solids" was improper, because it includes inventions containing solid content above the highest concentration disclosed in the specification, 60 % solid matter. *Id.* at 263. Because any claimed concentration above 60 % is outside the scope of

the description, one skilled in the art would not recognize such a claim as being part of the invention. *Id.*

In contrast, the court held that claims containing a concentration range of between 35 % and 60 % solid matter were proper, even though the claimed range was narrower than originally disclosed in the specification. *Id.* at 264. As long as the broader range disclosed in the specification also describes the narrower claimed range, one skilled in the art would recognize that both the broader disclosure and the narrower claims describe the same invention. *Id.* at 264-265. The claimed invention does not have to be described *in ipsis verbis* in order to satisfy the description requirement. *Id.* at 265.

Here, the Applicant's specification discloses the example of an atelocollagen solution cross-linked with cupric chloride and hydrogen peroxide and allowed to gel at 20 to 45 degrees Celsius. See ¶ [0028]. Thus the lower temperature of the added claim range at which the material is allowed to gel is explicitly disclosed in the specification. The upper temperature of the range originally disclosed in the specification example was 45 degrees Celsius. The upper temperature in the newly amended claims is 37 degrees Celsius. The upper temperature of the range in the claims was chosen to narrow the claims so that the claims were no longer anticipated by Berggren, and claim 18 of the extant application further indicates the significance of temperatures above 37 degrees Celsius.

Because one skilled in the art would recognize that the narrower temperature range of the newly amended claims includes temperature range at which the material is allowed to gel disclosed in the specification, the narrower temperature range of the amendments is properly supported by the specification. Like the narrower claim ranges in *In re Wertheim*, the claimed

temperature range here is contained within the range disclosed in the specification, and is thus a proper range.

The newly amended claims are not anticipated by Berggren. The material in Berggren must be heated to a "physiologically elevated temperature" of 38-75 degrees Celsius in order to be flowable and deliverable by syringe. Once the material disclosed in Berggren is cooled to body temperature (37 degrees Celsius), it cannot be a gel. Berggren, then, does not disclose a material that is allowed to gel at 20-37 degrees Celsius, as required in the newly amended claims, and the Applicant has overcome the Berggren 102(b) rejection.

35 U.S.C. § 102(b) Rejection: Smestad et al.

Claims 12 and 14 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,582,640 to Smestad *et al.* ("Smestad"). Smestad discloses a syringe comprising a flowable, moldable, biocompatible gel prepared by a collagen derivative and a non-cytotoxic cross-linking agent. However, because Smestad does not disclose a "bioresorbable" material, it does not anticipate claims 12 and 14.

For a reference to anticipate a claim, the reference must teach every element of the claim. MPEP § 2131. Each and every element of the claim must be found, either expressly or inherently in the reference. *Id.* Here, claim 12 and, by dependency, claim 14, claim a kit comprising among other things a "flowable, moldable, biocompatible, bioresorbable gel dressing" (underline added).

The specification defines a "bioresorbable" material as "one that breaks down over a finite period of time due to the chemical/biological action of the body." See ¶ [0022]. The specification further states that the dressing "is absorbed while conducting cell growth resulting

in uninterrupted regeneration of bone in the cavity. The dressing is bioresorbable by the human body..." See ¶ [0024]. The specification further states that the symptoms treated by the Applicant's invention can persist up to 30 days, and that the invention supplies a need for a dressing that "would not require removal." See ¶¶ [0006], [0012]. Thus, the specification implies that the bioresorbable material would be completely reabsorbed into the body without being removed some time after the 30-day persistence period of the condition being treated. However, the bioresorbable material would not persist too long beyond that time, or the material would require removal.

In contrast, the material disclosed in Smestad is used for dermal augmentation, and a principal object of the invention is to create an injectable material for dermal augmentation that has improved persistence (reduced solubility, enhanced resistance to proteolytic degradation) relative to other collagen implants known in the art (col. 2 lines 16-19). Indeed, an ideal dermal implant material forms implants that are not reabsorbed at all and thus do not shrink in volume over time (see col. 1 lines 64-68). Thus, the material disclosed in Smestad is specifically designed not to be bioresorbable, and Smestad does not explicitly or inherently disclose a bioresorbable material.

Because the material disclosed in Smestad is not bioresorbable, Smestad does not disclose all the elements of claims 12 and 14. Hence, Smestad does not anticipate those claims, and the applicant respectfully requests the examiner to reconsider the Smestad 102(b) rejection.

35 U.S.C. § 103(a) Rejection: Friedman in view of Berggren

Claims 1-2, 4-6, 8-9, 16, 19, 25-26, and 28-29 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,002,769 to Friedman ("Friedman ") in view of

U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren"). Friedman discloses cross-linked proteins such as gelatin and collagen for the sustained release of chlorhexidine to treat conditions such as pain and dry socket. OA at 4. Berggren, discussed in more detail above, discloses a flowable material for the delivery of drugs, including chlorhexidine. OA at 5. The Examiner states that Friedman would make it obvious to use the flowable material disclosed in Berggren to treat dry socket.

For two reasons, the Applicant requests to the examiner to reconsider these rejections. First, because of the new amendments, the combined references no longer disclose all the limitations of the rejected claims. Second, both references teach away from the present method, which uses a material that is allowed to gel and is flowable at or below body temperature.

One rationale supporting a *prima facie* conclusion of obviousness is the combining of prior art elements according to known methods to yield predictable results. See MPEP § 2143(A). The Examiner points out that all the elements of the rejected method claims are in the two references combined, and that it would be obvious to combine the references, as both methods can be used to deliver the same drug. OA at 5. However, neither of the references cited contains the new limitation that has been added to the rejected claims to overcome the previous anticipation rejection (the reaction mixture is allowed to gel at 20-37 degrees Celsius). Thus, the combined references no longer contain all the limitations of the rejected claims, and the claims are no longer *prima facie* obvious.

In addition, both cited references teach away from using a material such as the one claimed here that is allowed to gel at 20-37 degrees Celsius and is flowable at those temperatures. The gel compositions in Freidman are dried to make non-gel implants for dental treatments. Specifically, the implants are polymeric solids that form films or bullet shaped solids

(col. 4 line16-18). The specification states that when dried, the implants "must have a high enough concentration of protein to produce a non gel-like material having structural stability" (col. 7 lines 20-23). Thus, Friedman teaches away from using any material that is flowable or is allowed to gel at body temperature or below (including from 20-37 degrees Celsius).

As discussed above in the context of the claims rejected as being anticipated by Berggren, Berggren also teaches away from the use of any material that is flowable or is a gel at body temperature or below. Berggren teaches a method where the material is heated above body temperature to make the material flowable for injection purposes only. After the material is injected, it should cool to become a "less or non-flowable" drug-retaining matrix that is retained within a periodontal pocket, "unlike gels or solutions or other fluids." Thus Berggren also teaches away from using material that is flowable or is allowed to gel below 38 degrees Celsius.

Because the cited references combined do not disclose all the limitations of the rejected claims, and because the cited references teach away from using the methods of the rejected claims, the Applicant respectfully requests the examiner to reconsider this rejection.

35 U.S.C. § 103(a) Rejection: Friedman in view of Berggren in further view of Miller

Claims 7 and 17 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,002,769 to Friedman ("Friedman ") in view of U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren") in further view of U.S. Patent No. 6,509,031 to Miller, *et al.* ("Miller"). The Examiner repeats the arguments of the above section, pointing out in addition that Miller further discloses a wound sealant where peroxides are used as a cross-linking agent. OA at 5. Thus, Miller contains the limitation of claims 7 and 17 that were not included in the combined references Friedman and Berggren.

For two reasons, the Applicant requests to the examiner to reconsider these rejections. First, because of the new amendments, the combined references no longer disclose all the limitations of the rejected claims. Thus, this is no longer a case of adding "known ingredients to known compositions." Second, the references combined before Miller is applied teach away from the present method, which uses a material that is allowed to gel and is flowable at or below body temperature. The argument of these two points is contained in the previous section, and applies as well to this rejection.

Because the cited references combined do not disclose all the limitations of the rejected claims, and because the cited references teach away from using the methods of the rejected claims, the Applicant respectfully requests the examiner to reconsider this rejection.

35 U.S.C. § 103(a) Rejection: Friedman in view of Berggren in further view of Higashi

Claims 3, 10, 14, and 20 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,002,769 to Friedman ("Friedman ") in view of U.S. Patent No. 5,620,700 to Berggren *et al.* ("Berggren") in further view of U.S. Patent No. 4,906,670 Higashi, *et al.* ("Higashi"). The Examiner repeats the arguments of the "Friedman in view of Berggren" section above, pointing out in addition that Higashi further discloses a periodontal disease treatment comprising atelocollagen and a cross-linking agent. OA at 7. Thus, Higashi contains the limitation of claims 3, 10, 14, and 20 (atelocollagen) that were not included in the combined references Friedman and Berggren.

For two reasons, the Applicant requests to the examiner to reconsider these rejections. First, because of the new amendments, the combined references no longer disclose all the limitations of the rejected claims. Thus, this is no longer a case of adding "known ingredients to

known compositions." Second, the references combined before Higashi is applied teach away from the present method, which uses a material that is allowed to gel and is flowable at or below body temperature. The argument of these two points is contained in the "Friedman in view of Berggren" section above, and applies as well to this rejection.

Because the cited references combined do not disclose all the limitations of the rejected claims, and because the cited references teach away from using the methods of the rejected claims, the Applicant respectfully requests the examiner to reconsider this rejection.

Conclusion

It is believed that in light of the amendments presented and arguments made in this response, the entire application has been placed in condition for allowance.

Because this response has been filed within the shortened statutory period for response, no additional fees are believed due expect for the RCE fee. However, if any other fees are needed, please charge them to Deposit Account 17-0055.

Respectfully submitted,

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